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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,840	09/23/2005	Kaoru Seno	SHGN-19	5013

1473 7590 03/25/2008

ROPES & GRAY LLP
PATENT DOCKETING 39/361
1211 AVENUE OF THE AMERICAS
NEW YORK, NY 10036-8704

EXAMINER	
KIFLE, BRUCK	

ART UNIT	PAPER NUMBER
1624	

MAIL DATE	DELIVERY MODE
03/25/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,840	SENO ET AL.	
	Examiner	Art Unit	
	Bruck Kifle	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *1,2,19 and 27-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-18 and 20-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/19/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restrictions

Applicant's election of the species A-48, as defined in Table 1, page 83, in the reply filed on 01/07/08 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The claims lack unity of invention because compounds of formula (I) or (Ia) do not possess single structural element that is shared by all of the alternatives which is inventive. The common structural feature shared by all of the alternatives of formula (I), namely the pyrazolopyrimidine, is old. The common structural feature of formula I, is **not** a patentable advance over the prior art.

The special technical feature is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art. The feature is, thus, not special if it is known. That what is common here is the pyrazolopyrimidine which is known.

The elected species was not found and the search and examination were expanded to embrace the scope of claim 3.

Claims 1, 2, 19 and 27-30 are withdrawn from consideration because art was found (see MPEP 803.02.).

Applicants are advised of MPEP 803.02 Restriction - Markush Claims [R - 2], fourth and fifth paragraph, where is stated:

> "As an example, in the case of an application with a Markush - type claim drawn to the compound C - R, wherein R is a radical selected from the group consisting of A, B, C, D, and E, the examiner may require a provisional election of a single species, CA, CB, CC, CD, or CE. The

Markush - type claim would then be examined fully with respect to the elected species and any species considered to be clearly unpatentable over the elected species. If on examination the elected species is found to be anticipated or rendered obvious by prior art, the Markush - type claim and claims to the elected species shall be rejected, and claims to the non - elected species would be held withdrawn from further consideration. As in the prevailing practice, **a second action on the rejected claims would be made final**." (emphasis added).

On the other hand, should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended. If prior art is found that anticipates or renders obvious the Markush-type claim with respect to a non-elected species, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. The prior art search, however, will not be extended unnecessarily to cover all nonelected species. Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection, as by amending the Markush-type claim to exclude the species anticipated or rendered obvious by the prior art, the amended Markush-type claim will be reexamined. The prior art search will be extended to the extent necessary to determine patentability of the Markush-type claim. In the event prior art is found during the reexamination that anticipates or renders obvious the amended Markush-type claim, the claim will be rejected and the action made final. Amendments submitted after the final rejection further restricting the scope of the claim may be denied entry.

Claim Rejections - 35 USC § 112

Claims 3-18 and 20-26 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

i) The nature of the prodrug is unclear. Arriving at a prodrug requires research. One skilled in the art cannot say which derivative results in a prodrug without doing research. It is not proper to require research to understand the scope of a claim.

ii) The term "substituted" without saying which substituents are intended is indefinite. One skilled in the art cannot say which substituents are permitted and which ones are not.

iii) The term "heteroaryl" is indefinite because it is not known how many atoms are present, how many and what kind of heteroatoms are involved, what size ring is intended and how many rings are present.

iv) The term "heterocyclic" is indefinite because it is not known how many atoms make up the ring, which atoms are present and what kind of a ring (monocyclic, bicyclic, spiro, fused,

bridged, saturated, etc.) is intended. It is also unclear how many atoms are present, which atoms are present, what the degree of saturation is and which substituents are permitted when R_1 and R_2 together with the adjacent N atom form a heterocycle.

v) The pharmaceutical composition in claim 14 lacks the carrier.

vi) Claims 15-18 are improper claims. Are these compound claims (thereby being duplicates of claim 3) or are these pharmaceutical compositions (thereby duplicates of claim 15).

Claims 24-26 provide for the use of a compound, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 24-26 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd. App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claims 3-8 and 20-26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a pharmaceutical salt, does not reasonably provide enablement for solvates of the compound of formula I. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. Applicants have not shown how one skilled in the art can arrive at a given solvate. None of the compounds made are crystallized out

as solvates. Arriving at a given solvate is not routine experimentation because it is unpredictable. One cannot make any solvate of a compound.

Solvates or hydrates are different chemical entities, they are not just impurities included in a compound. Pharmaceutically acceptable salts are additions and therefore not the same. Additions are obvious variation "after" the compounds are obtained, thus, can be allowed with the compounds. Solvates or hydrates must be obtained at the time the invention was made. If Applicants do not have the solvates or hydrates at the time the invention was made, they are not in possession of them because they are unpredictable.

Claim 21 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 21 is drawn to a method of treating or preventing NAD(P)H-related diseases. The how to use portion of the statute has not been addressed. This means that Applicants must teach the skilled practitioner, in this case a physician, how to treat a given subject. The physician clearly must know what disease and what symptoms are to be prevented or treated. In this case, Applicants have not provided what is being treated by claim 21, who the subject is, how one can identify said subject (i.e. how one can identify a subject in need or the subject who has the potential to be afflicted by), given no specific dose, given no specific dosing regimen, given no specific route of administration, and do not specify what diseases or symptom they intend to treat.

Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. Tossing out the mere germ of an idea does not constitute enabling disclosure. Genentech Inc. v. Novo Nordisk 42 USPQ2d 1001.

As the Supreme Court said in *Brenner v. Manson*, 148 USPQ at 696: "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." As U.S. Court of Customs and Patent Appeals stated *In re Diedrich* 138 USPQ at 130, quoting with approval from the decision of the board: "We do not believe that it was the intention of the statutes to require the Patent Office, the courts, or the public to play the sort of guessing game that might be involved if an applicant could satisfy the requirements of the statutes by indicating the usefulness of a claimed compound in terms of possible use so general as to be meaningless and then, after his research or that of his competitors has definitely ascertained an actual use for the compound, adducing evidence intended to show that a particular specific use would have been obvious to men skilled in the particular art to which this use relates."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

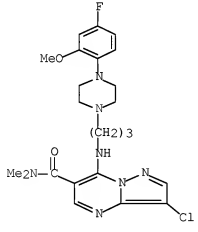
> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3, 4, 6, 7 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Elworthy et al. (Journal of Medicinal Chemistry (1997), 40(17), 2674-2687). See page 2686, the compound before last depicted below for Applicants convenience.

RN 193975-30-3 CAPLUS
CN Pyrazolo[1,5-a]pyrimidine-6-carboxamide, 3-chloro-7-[[3-[4-(4-fluoro-2-methoxyphenyl)-1-piperazinyl]propyl]amino]-N,N-dimethyl-, ethanedioate (1:2) (CA INDEX NAME)

CM 1

CRN 193975-29-0
CMF C23 H29 Cl F N7 O2

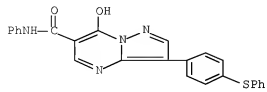


CM 2

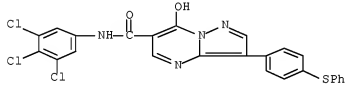
CRN 144-62-7
CMF C2 H2 O4

Claim 20 is rejected under 35 U.S.C. 102(b) as being anticipated by Kiyokawa et al. (US 5,420,128). The claims read on the compounds depicted below.

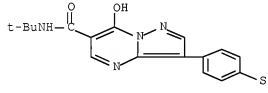
RN 142664-57-1 CAPLUS
CN Pyrazolo[1,5-a]pyrimidine-6-carboxamide, 7-hydroxy-N-phenyl-3-[4-(phenylthio)phenyl]- (CA INDEX NAME)



RN 142664-60-6 CAPLUS
CN Pyrazolo[1,5-a]pyrimidine-6-carboxamide, 7-hydroxy-3-[4-(phenylthio)phenyl]-N-(3,4,5-trichlorophenyl)- (CA INDEX NAME)



RN 142664-61-7 CAPLUS
CN Pyrazolo[1,5-a]pyrimidine-6-carboxamide, N-(1,1-dimethylethyl)-7-hydroxy-3-4-(phenylthio)phenyl]- (CA INDEX NAME)



These compounds are excluded from claim 3. The intended use of claim 20 does not have patentability weight.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruck Kifle whose telephone number is 571-272-0668. The examiner can normally be reached on Mondays-Fridays from 8:30 AM -6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bruck Kifle/
Primary Examiner
Art Unit 1624

BK
March 20, 2008